

HOT AND COLD MEDICATED PATCH- menthol patch

Veridian Healthcare

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hot and Cold Medicated Patch

ACTIVE INGREDIENT

Active Ingredient	Purpose
Menthol 5%.....	Topical Analgesic

INACTIVE INGREDIENT

Water, Glycerin, Sodium Polyacrylate, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Titanium Dioxide, Kaolin, Tartaric Acid, Dihydroxyaluminum Aminoacetate, Methylparaben, Propylparaben, PVP

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control

INDICATIONS & USAGE

Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis ■ muscle strains ■ muscle sprains ■ bruises ■ cramps

WARNINGS

For External Use Only.

DOSAGE & ADMINISTRATION

Adults and children over 12 years: Carefully remove backing from patch. Apply sticky side of patch to affected area.

Wear one patch up to 8 hours. Repeat as necessary, but no more than 4 times daily. Reseal pouch after opening.

Children 12 years or younger: Consult a physician.

PURPOSE

Topical Analgesic

When using this product

Use only as directed ■ Don't bandage tightly or use with heating pad

■ Avoid contact with eyes and mucous membranes ■ Don't apply to wounds or damaged skin.

Stop use and ask a doctor

If condition worsens ■ If redness is present ■ If irritation develops

- If symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breastfeeding

ask a health professional before use.

Manufactured For
Veridian Healthcare, LLC
Gurnee, IL 60031

TOLL-FREE CUSTOMER CARE HELP LINE Mon–Fri, 8:30 am–4:30 pm CST 866-326-1313



HOT AND COLD MEDICATED PATCH			
menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7110 1-952
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	5 g in 100 g
---	---------	--------------

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINO ACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05I15JN12J)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-952-15	15 in 1 BOX	05/01/2018	
1		9 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2018	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(71101-952)

Revised: 5/2018

Veridian Healthcare